

ATTACHMENT 2

Draft Guidance for Industry: “Combined Oral Contraceptives – Labeling for Healthcare Providers and Patients”

Guidance for Industry

Combined Oral Contraceptives – Labeling for Healthcare Providers and Patients

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication of the *Federal Register* notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions on the content of the draft document contact Lana L. Pauls, 301-827-4260.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
June 2000
Labeling**

42 **Guidance for Industry**
43
44 **Combined Oral Contraceptives –**
45 **Labeling for Healthcare Providers**
46 **and Patients**

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51 *Additional copies of this Guidance are available from:*
52

53
54
55 *Drug Information Branch, HFD-210*
56 *Center for Drug Evaluation and Research*
57 *Food and Drug Administration*
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60 *Internet: <http://www.fda.gov/cder/guidance/index.htm>.*
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79 **U.S. Department of Health and Human Services**
80 **Food and Drug Administration**
81 **Center for Drug Evaluation and Research (CDER)**
82 **June 2000**
83 **Labeling**
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147 **I. INTRODUCTION**
148

149 This draft guidance is an update of a guidance published in August 1994. It describes the
150 recommended labeling for healthcare providers and patient instructions for use for new drug
151 applications (NDAs) and abbreviated new drug applications (ANDAs) for combined oral
152 contraceptives (those that contain estrogen and progestin).
153

154
155 **II. LABELING FOR HEALTHCARE PROVIDERS**
156

157 For combined oral contraceptives (COCs), the recommended text of the prescribing
158 information for healthcare providers is as follows:
159

WARNING – CIGARETTE SMOKING

Cigarette smoking increases the risk of serious cardiovascular side effects from COC use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use COCs should be strongly advised not to smoke.

160
161
162 **PROPRIETARY NAME** (*Established Name*)
163

164 *Supplied by manufacturer*
165

166 **Women should be informed that this product does not protect against infection from**
167 **HIV (the virus that causes AIDS) or other sexually transmitted diseases.**
168
169
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171

¹ This guidance has been prepared by the Division of Reproductive and Urologic Drug Products in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration. This guidance document represents the Agency's current thinking on combined oral contraceptive labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both.

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DESCRIPTION

Supplied by Manufacturer.

CLINICAL PHARMACOLOGY

Mode of action

The primary mechanism by which combined estrogen-progestin oral contraceptives prevent conception is suppression of ovulation. Other possible mechanisms include changes in the cervical mucus that inhibit sperm penetration and alterations of the endometrium that reduce the likelihood of implantation.

Pharmacokinetics

Supplied by Manufacturer.

INDICATIONS AND USAGE

Indications

Combined oral contraceptives (COCs) are indicated for the prevention of pregnancy.

Other approved indications to appear here, as well (e.g., acne).

Efficacy

If COCs are used as recommended in their approved labeling, the chance of becoming pregnant during the first year of use is 0.1 percent. However, typical pregnancy rates are estimated to be 5 percent (Table 1 - Trussell et al. 1998). Rates of effectiveness vary by factors that affect ability to conceive (including age), frequency of sexual intercourse, and how correctly and consistently the method is used.

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Table 1: Percentage of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of contraception and the percentage continuing use at the end of the first year. United States.

Method (1)	% of Women Experiencing an Unintended Pregnancy within the First Year of Use		% of Women Continuing Use at One Year ³ (4)
	Typical Use ¹ (2)	Perfect Use ² (3)	
Chance ⁴	85	85	
Spermicides ⁵	26	6	40
Periodic abstinence	25		63
Calendar		9	
Ovulation Method		3	
Symptom-thermal ⁶		2	
Post-Ovulation		1	
Cap ⁷			
Parous Women	40	26	42
Nulliparous Women	20	9	56
Sponge			
Parous Women	40	20	42
Nulliparous Women	20	9	56
Diaphragm ⁷	20	6	56
Withdrawal	19	4	
Condom ⁸			
Female (Reality)	21	5	56
Male	14	3	61
Pill	5		71
Progestin only		0.5	
Combined		0.1	
IUD			
Progesterone T	2.0	1.5	81
Copper T 380A	0.8	0.6	78
LNg 20	0.1	0.1	81
Depo-Provera	0.3	0.3	70
Norplant and Norplant 2	0.05	0.05	88
Female Sterilization	0.5	0.5	100
Male Sterilization	0.15	0.10	100

Emergency Contraceptive Pills: Treatment initiated within 72 hours after unprotected intercourse reduces the risk of pregnancy by at least 75%.⁹

Lactational Amenorrhea Method: LAM is a highly effective, *temporary* method of contraception.¹⁰

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Table 1, cont.

Source: Trussell, J., "A Contraceptive Efficacy," in R.A. Hatcher, J. Trussell, F. Stewart, W. Cates, G.K. Stewart, F. Guest, D. Kowal, 1998, *Contraceptive Technology: Seventeenth Revised Edition*, Irvington Publishers.

- 1 Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason
- 2 Among couples who initiate use of a method (not necessarily for the first time), and who use it perfectly (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason
- 3 Among couples attempting to avoid pregnancy, the percentage who continue to use a method for one year
- 4 The percentage of women becoming pregnant noted in columns (2) and (3) are based on data from populations where contraception is not used and from women who cease using contraception in order to become pregnant. Among such populations, about 89% become pregnant within one year. This estimate was lowered slightly (to 85%) to represent the percentage that would become pregnant within one year among women now relying on reversible methods of contraception if they abandoned contraception altogether.
- 5 Foams, creams, gels, vaginal suppositories, and vaginal film
- 6 Cervical mucus (ovulation) method supplemented by calendar in the preovulatory and basal body temperature in the postovulatory phases
- 7 With spermicidal cream or jelly
- 8 Without spermicides
- 9 The treatment schedule is one dose within 72 hours after unprotected intercourse, and a second dose 12 hours after the first dose. The Food and Drug Administration has declared the following brands of oral contraceptives to be safe and effective for emergency contraception: Ovral (1 dose is 2 white pills), Alesse (1 dose is 5 pink pills), Nordette or Levlen (1 dose is 2 light orange pills), Lo/Ovral (1 dose is 4 white pills), Triphasil or Tri-Levlen (1 dose is 4 yellow pills) (62 FR 8612; February 25, 1997).*
- 10 However, to maintain effective protection against pregnancy, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breastfeeds is reduced, bottle feeds are introduced, or the baby reaches six months of age.

*Alesse was approved as safe and effective for emergency contraception subsequent to the February 1997 *Federal Register* notice.

CONTRAINDICATIONS

Deep vein thrombosis (current or history)
Pulmonary embolism (current or history)
Ischemic heart disease (current or history)
History of cerebrovascular accidents
Valvular heart disease with complications
Severe hypertension
Diabetes with vascular involvement
Headaches with focal neurological symptoms
Major surgery with prolonged immobilization.

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Known or suspected carcinoma of the breast or personal history of breast cancer
Liver tumors (benign and malignant), active liver disease
Known or suspected pregnancy
Heavy smoking (≥ 15 cigarettes per day) and over age 35

Use is contraindicated in women who are known to be hypersensitive to any component of this product.

WARNINGS

1. Cardiovascular disease

COC use is associated with an increase in the incidence of cardiovascular disease, primarily because of an increased risk of thrombosis, rather than through an atherogenic mechanism. The degree of risk appears to be related primarily to the estrogen dosage. This increased risk is limited to the period of COC use and disappears on cessation of use.

a. Deep vein thrombosis, pulmonary embolism

Use of COCs is associated with a risk of venous thromboembolism which is 3 to 6 times higher than that among nonusers. Smoking does not appear to contribute to the risk of venous thromboembolic events.

For products containing desogestrel:

Data from case-control and cohort studies report that oral contraceptives containing desogestrel are associated with a twofold increase in the risk of venous thromboembolic diseases as compared to other low-dose pills containing other progestins. According to these studies, this twofold risk increases the yearly occurrence of venous thromboembolic disease by about 10-15 cases per 100,000 women.

The presence of factor V Leiden mutation and other hereditary coagulation disorders increases the risk of thromboembolic disease.

COC use is contraindicated for women who have active deep venous thrombosis or pulmonary embolism and for those who have a history of these conditions in association with estrogen use.

Women who are immobilized for prolonged periods because of major surgery should not use COCs. For women undergoing surgery without prolonged immobilization, the advantages of COC use generally outweigh the risk.

COC use should preferably not begin until 2-3 weeks postpartum, because of the risk of thrombosis.

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b. Cerebrovascular disease

In women who do not smoke and do not have hypertension, the risk of ischemic stroke in users of COCs is increased by about 1.5 times compared with nonusers. The likelihood of hemorrhagic stroke is not increased among users of low-dose combined COCs who are under 35 years old and do not smoke or have hypertension. Women who have a history of stroke should not use COCs.

The likelihood of myocardial infarction (MI) is not increased among young women who use COCs and do not smoke or have hypertension or diabetes. Heavy smokers (≥ 15 cigs/day) older than 35 years should not take COCs. Women who currently have ischemic heart disease, or who have a history of this disease, should not use COCs due to an increased risk of MI and stroke.

c. Valvular heart disease

COC use is contraindicated for women whose valvular heart disease is complicated by such factors as pulmonary hypertension, atrial fibrillation, or history of subacute bacterial endocarditis. COC use may be acceptable for women with uncomplicated valvular heart disease.

2. Elevated blood pressure

For women with an elevation in blood pressure ($160+/100+$ mm/Hg), COC use would present an unacceptable health risk, and COCs should not be used. Similarly, hypertensive women with vascular disease should not use COCs.

3. Carbohydrate metabolism

For women with diabetes (both insulin-dependent and non-insulin-dependent), who do not have vascular involvement, the advantages of COC use generally outweigh the risks, particularly in light of the risks associated with pregnancy in these women. The major concerns of COC use by this population are vascular disease and an added risk of thrombosis, although COC use by diabetic women appears to have only minimal effects on lipid metabolism and hemostasis. For diabetic women with nephropathy, retinopathy, neuropathy, or other vascular involvement, the risk-benefit ratio depends on the severity of the condition.

4. Lipid metabolism

Because some hyperlipidemias are risk factors for vascular disease, the appropriateness of COC use is dependent on the type and severity of known hyperlipidemias.

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5. Headaches

For women with severe, recurrent headaches, including migraine headaches, the appropriateness of using COCs depends on the presence or absence of focal neurologic symptoms. These symptoms may reflect an increased risk of stroke and COC use is contraindicated in patients in whom they are present. The onset or exacerbation of migraines or the development of severe recurrent or persistent headache with focal neurological symptoms requires discontinuation of COC use and evaluation of the cause of the headaches.

6. Unexplained vaginal bleeding

Women who have unexplained vaginal bleeding suggestive of an underlying pathological condition or pregnancy should be evaluated prior to initiation of COC use to avoid confusion of the potentially pathologic bleeding with a possible COC side effect.

Mild bleeding irregularities are common among women taking COCs, particularly during the early months of use. However, if the bleeding pattern of a COC user is suggestive of pathology or pregnancy, diagnostic measures should be taken to rule out these other causes; meanwhile, the benefits of continued COC use generally outweigh the risks.

7. Breast cancer

Although the risk of breast cancer may be slightly increased among current and recent users of COCs, this excess risk decreases over time after COC discontinuation and by 10 years after cessation the increased risk disappears. The risk does not increase with duration of use, and no relationships have been found with dose or type of steroid. The patterns of risk are also similar regardless of a woman's reproductive history or her family breast cancer history. The subgroup for whom risk has been found to be significantly elevated is women who first used COCs before age 20, but because breast cancer is so rare at these young ages, the number of cases attributable to this early COC use is extremely small.

Breast cancers diagnosed in current or previous OC users tend to be less invasive than in nonusers.

Women who currently have or have had breast cancer should not use COCs because breast cancer is a hormone-sensitive tumor.

8. Cervical cancer

Some reports indicate a statistical association between COC use and cervical cancer, but several important methodological problems are inherent in studying this relationship, and the association remains unclear.

9. Gallbladder disease

COCs may worsen existing gallbladder disease and may accelerate the development of this disease in previously asymptomatic women.

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Women with a history of COC-related cholestasis are more likely to have the condition recur with subsequent COC use.

10. Liver disease

Because steroid hormones are metabolized by the liver, women taking COCs may experience adverse hepatobiliary effects. Although case-control studies have indicated that the risk of both benign and malignant liver tumors may be slightly increased by COC use, the incidence of these tumors potentially attributable to COCs in the United States is minimal because the disease is very rare.

Women who currently have active liver disease should not use COCs.

PRECAUTIONS

1. Sexually transmitted diseases

Women should be informed that this product does not protect against infection from HIV (the virus that causes AIDS) or other sexually transmitted diseases (STDs), except symptomatic pelvic inflammatory disease. If a woman is at high risk for STDs she should be encouraged to reduce risky behavior and to use condoms or other barrier methods in addition to COCs.

Clinically apparent pelvic inflammatory disease (PID) is less common in women taking COCs. Whether this reflects a protective or a masking effect of COCs is not known. COCs provide no protection against lower reproductive tract infection and appear to be associated with increased risk of infection with *Chlamydia trachomatis*. The risk of acquiring HIV infection in COC users is uncertain, with some studies showing an increased risk with COC use and others finding no association.

2. Physical examination and follow-up

Before initiating COC use, blood pressure should be measured and details of the woman's personal and family medical history should be obtained. Blood pressure should be measured periodically during COC use and additional clinical evaluation should be based on these initial and follow-up findings.

3. Drug Interactions

The efficacy of COCs is reduced by hepatic enzyme-inducing drugs such as the antituberculosis drug rifampin and the anticonvulsants phenytoin, carbamazepine, and barbiturates. The efficacy of COCs when used with griseofulvin may also be reduced.

The following section contains information on drug interactions with ethinyl estradiol-containing products that have been reported in the public literature. It is unknown whether such interactions occur with drug products containing other types of estrogens.

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- a. The metabolism of ethinyl estradiol is increased by rifampin and anticonvulsants such as phenobarbital, phenytoin, and carbamazepine. Coadministration of troglitazone and certain ethinyl estradiol-containing drug products (e.g., oral contraceptives containing ethinyl estradiol) reduce the plasma concentrations of ethinyl estradiol by 30 percent.

Ascorbic acid and acetaminophen may increase AUC and/or plasma concentrations of ethinyl estradiol. Coadministration of atorvastatin and certain ethinyl estradiol-containing drug products (e.g., oral contraceptives containing ethinyl estradiol) increase AUC values for ethinyl estradiol by 20 percent.

Clinical pharmacokinetic studies have not demonstrated any consistent effect of antibiotics (other than rifampin) on plasma concentrations of synthetic steroids.

- b. Drug products containing ethinyl estradiol may inhibit the metabolism of other compounds. Increased plasma concentrations of cyclosporin, prednisolone, and theophylline have been reported with concomitant administration of certain drugs containing ethinyl estradiol (e.g., oral contraceptives containing ethinyl estradiol). In addition, drugs containing ethinyl estradiol may induce the conjugation of other compounds.

4. Interactions that affect laboratory tests

The following tests may be affected by COC use, with the direction and magnitude of the effect dependent in part on the type and dose of the steroids:

- a. Sex hormone-binding globulin (SHBG) concentrations may be increased and result in elevated levels of total circulating sex steroids and corticoids; however, free or biologically active levels of the sex steroids remain unchanged.
- b. Glucose tolerance may be impaired and insulin levels increased (see CARBOHYDRATE METABOLISM).
- c. Triglycerides may be increased, and levels of various other lipids and lipoproteins may be affected (see LIPID METABOLISM).
- d. Various parameters of coagulation and fibrinolytic activity may be affected.
- e. Thyroid-binding globulin (TBG) and protein-bound iodine (PBI) may be increased; T3 resin uptake may be decreased. Other binding globulins (corticosteroid binding globulin/CBG, ceruloplasmin, cortisol) may also be elevated in serum.

5. Carcinogenesis

See WARNINGS.

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6. Pregnancy

Extensive research has found no significant effects on fetal development associated with long-term use of contraceptive doses of oral contraceptive steroids before pregnancy or if taken inadvertently during early pregnancy.

7. Nursing mothers

COCs given in the postpartum period may interfere with lactation by decreasing the quantity of breast milk and by affecting its composition. Oral contraceptive steroids have been reported in the milk of breast-feeding mothers with no apparent clinical significance; long-term follow-up of children whose mothers used COCs while breast-feeding has shown no deleterious effects. However, women who are fully breast-feeding should not start taking COCs until 6 weeks postpartum.

8. Fertility following discontinuation

Conception may be delayed an average of 1-2 months among women stopping COCs compared to women stopping nonhormonal contraceptive methods.

9. Pediatric use

Safety and efficacy of [drug] have been established in women of reproductive age. Safety and efficacy are expected to be the same for postpubertal adolescents under 16 years of age and users 16 years of age and older. Use of this product before menarche is not indicated.

10. Information for the patient

Please see separate patient labeling.

ADVERSE EXPERIENCES

The most serious adverse reactions associated with the use of COCs are discussed above in the WARNINGS section. Others are presented in the PRECAUTIONS section.

Other side effects commonly reported by COC users are:

- Nausea
- Breast tenderness
- Headaches

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607 Less frequently, the following adverse reactions may occur:
608

- 609 • Vomiting and other gastrointestinal symptoms (e.g., bloating)
 - 610 • Mood changes and depression
 - 611 • Decreased libido
 - 612 • Acne
 - 613 • Dizziness
 - 614 • Weight gain (or loss)
 - 615 • Melasma
 - 616 • Increased cervical ectopia
 - 617 • Vaginal candidiasis
 - 618 • Fluid retention
 - 619 • Ocular effects, including decreased tolerability to contact lenses
- 620

621 It is not always clear whether these side effects are causally associated with COCs and, if so,
622 whether the estrogen and/or the progestin is responsible. These side effects tend to be most
623 common in the first 1-3 pill cycles, with the prevalence declining thereafter.
624

625 Some COC users have breakthrough bleeding or spotting, although this side effect generally
626 improves over time. Breakthrough bleeding is somewhat more likely to occur following a
627 missed pill. More rarely, prolonged bleeding or amenorrhea can occur. However, most
628 women experience beneficial changes in menstrual cycle patterns (see
629 NONCONTRACEPTIVE HEALTH BENEFITS).
630

631 *Manufacturers may want to add additional details regarding adverse experiences and cycle*
632 *control.*
633

634 **NONCONTRACEPTIVE HEALTH BENEFITS**
635

636 During the time that women are taking COCs, many experience the following improvements
637 in menstrual parameters:
638

- 639 • Increased menstrual cycle regularity
 - 640 • Decreased blood loss and decreased prevalence of iron deficiency anemia
 - 641 • Decreased prevalence and severity of dysmenorrhea
- 642

643 Other beneficial effects that may be experienced during COC use include the following:
644

- 645 • Decreased incidence of delayed follicular atresia (functional ovarian cysts)
 - 646 • Decreased incidence of ectopic pregnancy
- 647

648 Epidemiological studies suggest that some beneficial effects begin during COC use and
649 persist for many years after COC discontinuation. These include:
650
651
652
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- 657
658
 - Decreased incidence of endometrial cancer

659
 - Decreased incidence of ovarian cancer

660
 - Decreased incidence of benign breast tumors

661

662 **OVERDOSAGE**
663

664 There have been no reports of serious ill effects from overdosage, including ingestion by
665 children. Overdosage may cause nausea, and withdrawal bleeding may occur in females.
666

667 **DOSAGE AND ADMINISTRATION**
668

669 To achieve maximum contraceptive effectiveness, COCs must be taken as directed. One
670 tablet is to be taken every day, preferably at the same time. Single missed pills should be
671 taken as soon as remembered. If 2 or more pills are missed, backup contraception should be
672 used until pills have been taken for 7 consecutive days. For more specific instructions, see
673 INSTRUCTIONS FOR USE.
674

675 **HOW SUPPLIED**
676

677 *Manufacturer to provide information on available dosage forms, potency, color, and*
678 *packaging.*
679

680 **STORAGE**
681

682 *Manufacturer to provide information on pill storage.*
683

684 **III. PATIENT LABELING (INSTRUCTIONS FOR USE)**
685

686 **HOW TO TAKE THE PILL (21-Day or 28-Day Pack)**
687

688 **BEFORE STARTING THE PILL**
689

690 **Be sure to read these directions:**
691

- 692
 - Before you start taking your pills

693
 - Anytime you are not sure what to do

694

695 **If you have further questions about taking these pills:**
696

- 697
 - CALL your healthcare professional or clinic for help [or call 1-800-XXX-XXXX].

698

699 **Check your pill pack.**
700

701 **The 21-day pill pack includes:**
702
703

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- 21 [color(s)] *active* hormonal pills to take for the first 3 weeks
These pills will be followed by 1 week without pills.

The 28-day pill pack includes:

- 21 [color(s)] *active* hormonal pills to take for the first 3 weeks.
- 7 [color] *reminder* pills (with no hormones) to take the 4th week

Check the picture of the pill pack below for:

- Which pill to take first
- The direction in which to take the pills
- The week numbers and pill colors

[INSERT PILL PACK PICTURE HERE]

Be sure you have two things ready at all times:

- Another kind of birth control, such as condoms, to use as a backup method in case you miss two or more pills in a row
- An extra, full pack of pills, in case you can't pick up the next pack when you need it

MOST IMPORTANT TO REMEMBER

You need to take a pill every day until the pack is empty. If possible, take the pill at the same time each day.

Do not skip taking pills even if:

- You have some spotting of blood between your periods
- You feel a little nauseated or sick to your stomach (If you do have nausea, it may be best to take your pills in the evening, after supper.)
- Your sexual activity varies from week to week

If you miss 2 or more pills in a row, use a backup method of birth control, such as condoms, any time you have sexual intercourse until you have taken the [color(s)] hormonal pills again for 7 days in a row.

When you finish a pack:

- **If you are using the 21-day pack,** wait 7 days before starting the next pack..

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- **If you are using the 28-day pack**, start the next pack the next day. Do not skip any days between pill packs.

OTHER IMPORTANT INFORMATION

Each day you miss taking a [color] hormonal pill increases your chance of getting pregnant.

Starting a pack late is actually riskier than missing pills later in the cycle. If you do start a pack late for any reason, follow the rules for missing the [color] hormonal pills, described below.

If you forget more than one [color] hormonal pill two months in a row, talk to your healthcare professional or clinic about:

- How to make pill-taking easier, or
- Using another method of birth control

If you are using the 21-day pack, your menstrual period will probably start in the week following the last day of pill use.

If you are using the 28-day pack, your menstrual period will probably start during the week that you take the reminder [color(s)] pills.

Your menstrual period may also tend to be shorter and much lighter than before you started taking the pill.

If you do miss a period, it is unlikely that you are pregnant, especially if you have been taking the pills every day and/or using condoms as a backup method of birth control.

However:

- Keep taking one pill each day, as usual.
- If you have missed two or more pills in the past month and have not used a backup method of birth control, you may want to consider taking a pregnancy test.

If you miss two periods in a row: Call your healthcare professional or clinic for a pregnancy test, even if you have taken your pills every day.

WHEN TO START YOUR FIRST PACK OF PILLS

Decide whether you want to start your first pack on the *first day* of your menstrual period or on *another day*, such as Sunday. The difference between these two options is:

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First day of your period	Sunday (or another day)
You do not need to use a backup method.	You need to use a backup method of birth control such as condoms until you have taken hormonal [color(s)] pills 7 days in a row – unless that day is also the first day of your period.

After a miscarriage or abortion, you can start taking the pill right away if the miscarriage or abortion occurred less than 20 weeks (or halfway) into the pregnancy. If the miscarriage or abortion occurred after 20 weeks, consult your clinician or healthcare professional about when to start taking the pill.

IF YOU'VE JUST HAD A BABY

If you are fully breast-feeding (not giving your baby any other source of milk or not giving your baby any food or formula), wait to start taking combined pills until your baby is at least 6 weeks old or until your menstrual periods begin, whichever comes first. The pills may slightly reduce your breast milk supply. You should start your pills by 6 months, even if you haven't yet had a menstrual period.

If you are partially breast-feeding (giving your baby some food or formula), begin taking your pills when you begin giving your baby other formula or foods. Check with your healthcare provider if you have not had a menstrual period.

If you are not breast-feeding, you can start taking your pills 2-3 weeks after the delivery of your baby.

STOPPING OR SWITCHING METHODS

If you want to stop using birth control pills (to get pregnant, for example):

- You can stop taking your pills at any time.
- Waiting until the end of a pack causes the least change in your monthly menstrual cycle.
- If there is a chance that you will start taking the pill again in the next few months, you might consider not stopping the pill at all.

If you only want to change the brand:

- You can start the new brand any time, but preferably when you start the next pack.

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If you switch to combined birth control pills from another method:

- Be sure to continue using the other method until the day you want to start taking the pill.
- Follow the instructions for **When to Start Your First Pack of Pills**, above.

If you switch from combined birth control pills to another method:

- **If you use the 21-day pack**, start the other method the day after you finish all of your pills.
- **If you use the 28-day pack**, start the other method after you finish all of the [color(s)] hormonal pills.

MISSED PILLS

The more pills you miss, the greater your risk of getting pregnant.

If you miss *one* pill of the 21-day pack or one [color(s)] *hormonal pill* of the 28-day pack:

- Take the missed pill as soon as you remember.
- Take the next pill at the regular time. *This means you may take 2 pills in one day.*

You do not need to use a backup birth control method.

If you miss *two or more* [color(s)] hormonal pills in a row during the first two weeks of pill use (21-day or 28-day pack) or if you are two or more days late starting a pack (21-day or 28-day pack):

- *Most important:* Use backup birth control (such as condoms) until you have been back on the hormonal pills for 7 days in a row.
- Don't try to make up the [color(s)] hormonal pills you missed; throw them out instead.
- Take one [color(s)] hormonal pill now, then keep taking one [color(s)] hormonal pill each day until they are gone.

If you are using the 28-day pack and you forget to take any of the 7 [color] reminder pills:

- Throw out the [color] reminder pills that you missed.
- Keep taking one [color] reminder pill until your regular new pack start day.

You do not need any backup method of birth control.

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IF YOU ARE TAKING OTHER MEDICINES, it is important to tell your doctor or clinic.

- A few medicines can make the pill less effective, especially certain medicines for seizures (epilepsy) or tuberculosis (TB).
- Antibiotics are rarely a problem, but it is a good idea to use a backup method of birth control just in case.
- Any time you get another kind of prescription from another healthcare provider, tell that healthcare provider that you are taking birth control pills.

IF YOU HAVE SEVERE VOMITING within 3 hours of taking your pill, it may not work as well. Take a second pill. If you vomit more than once, it may be safest to use a backup method for the next 7 days. Call your healthcare professional or clinic for further advice.

OTHER GENERAL INFORMATION

- Do not share your pills with anyone else.

A FINAL REMINDER

Anytime you are not sure what to do about the pills you have missed or if you have any other questions, CALL your healthcare professional or clinic OR call 1-XXX-XXX-XXXX.

Until you have the information you need:

- Use backup birth control, such as condoms, anytime you have sex **AND**
- Keep taking one pill each day.

You can also ask for the more detailed professional labeling written for doctors and other healthcare providers.

For references, see the professional product labeling